REMARKS

Claims 41, 44, 46 and 55-58 are pending in the subject application. No claim has been added, canceled, or amended herein. Accordingly, claims 41, 44, 46 and 55-58 are still pending and under examination.

Rejections under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 41, 44, 46 and 55-56 under 35 U.S.C. §112, first paragraph, as allegedly not enabled.

In response, applicants respectfully traverse the Examiner's rejection. In support of their traversal, applicants incorporate their remarks regarding enablement made in the July 9, 2002 and January 7, 2002 Amendments, and make the following additional remarks to underscore their position.

Claim 41, and dependent claims 44, 46 and 55-56, provide a method of inhibiting the binding of a β-sheet fibril to RAGE on the surface of a cell of a subject, wherein the cell is located outside the central nervous system of the subject, which comprises contacting the cell with a compound that inhibits binding of the β-sheet fibril to RAGE.

The Examiner maintains that there is no link in the disclosure that connects the inhibition of amyloid in splenic cells of mice to a method of treating a subject or disease *in vivo*, as applicable to

human beings.

The test for enablement under 35 U.S.C. §112, first paragraph, is whether the disclosure contains sufficient information regarding the subject matter of the claims to enable one skilled in the relevant art to practice the claimed invention without undue experimentation.

Applicants are not aware of any requirement under 35 U.S.C. §112, first paragraph, that mandates providing human experimental data in the specification in order to enable the subject claims. Applicants maintain that the disclosed mouse models are an adequate representation of human amyloidosis and can be used as a model of treatment for Alzheimer's disease using the methods of the subject invention. The Examiner has not cited any art which indicates that such data are insufficient for enabling the subject claims.

Applicants therefore assert that human data are not required and that the experimental data disclosed in the subject application are sufficient to enable pending claims 41, 44, 46 and 55-56. Indeed, section 2164.02 of the M.P.E.P. states that an "*in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a `working example' if that example `correlates' with a disclosed or claimed method invention." It is well known in the art that amyloid deposition is involved in or causative of diseases in numerous organisms, including Alzheimer's disease in humans. Applicants assert that at the very least, the use of soluble RAGE to inhibit binding of amyloid to splenic cells in mice "correlates"

to the use of such inhibitors in treating amyloidosis-related disease in humans.

The Examiner has failed to set forth any art indicating a lack of correlation between the animal model example disclosed in the specification and the claimed methods.

Accordingly, applicants maintain that claims 41, 44, 46 and 55-56 satisfy the requirements of 35 U.S.C. §112, first paragraph.

The Examiner also rejected claims 57 and 58 under 35 U.S.C. §112, first paragraph, as allegedly not enabled.

In response, applicants respectfully traverse the Examiner's rejection. In support of their traversal, applicants incorporate their remarks made in the July 9, 2002 and January 7, 2002 Amendments regarding enablement, and make the following additional remarks to underscore their position.

Claim 57 provides a method of inhibiting the binding of a β-sheet fibril to RAGE on the surface of a cell of a subject, wherein the cell is located outside the central nervous system of the subject, which comprises administering to the subject an amount of soluble RAGE (sRAGE) effective to inhibit binding of the β-sheet fibril to RAGE.

Claim 58 provides a method of inhibiting the binding of a β-sheet fibril to RAGE on the surface of a cell of a subject, wherein the

cell is located outside the central nervous system of the subject, which comprises administering to the subject an amount of a peptide fragment of sRAGE identical to the V-domain of sRAGE effective to inhibit binding of the β-sheet fibril to RAGE.

Specifically, the Examiner maintains that the specification does not disclose the nexus that would enable the methods of the claimed invention to be applied to Alzheimer's disease or a disease related to amyloidosis or to inhibiting the binding of ligand to RAGE in a diseased subject.

Again, the test for enablement is whether the disclosure contains sufficient information to enable one skilled in the relevant art to practice the claimed invention without undue experimentation.

Applicants maintain that the disclosure is sufficient to enable one skilled in the art to practice the claimed methods of binding inhibition. Applicants further assert that for enablement, the description need not set forth the detailed chemical mechanism by which inhibition of β-sheet fibril binding results in the treatment of Alzheimer's disease or a related disease in humans. The fact that these methods could be practiced based on the specification is sufficient.

For the above reasons, applicants maintain that claims 57 and 58 satisfy the provisions of 35 U.S.C. §112, first paragraph.

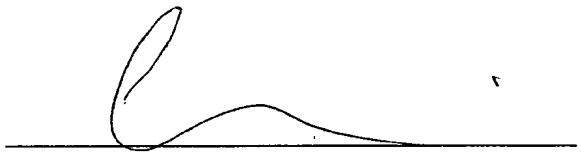
Summary

Based on the reasons set forth hereinabove, applicants maintain that the pending claims are in condition for allowance. Accordingly, allowance is respectfully requested.

No fee, other than the $55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Respectfully submitted,



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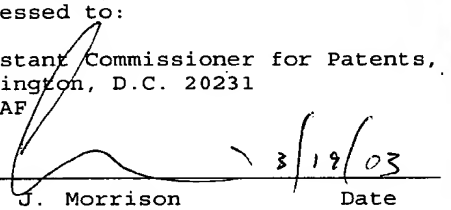

3/19/03

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